- the research is related to health and wellbeing; and
- the experience of Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
- data collection is explicitly directed at Aboriginal people; or
- research outcomes explicitly related to Aboriginal people; or
- it is proposed to conduct sub-group analysis or separately analyse Aboriginal people in the results; or
- the information, potential over-representation in the dataset, or geographic location has an impact on one or more Aboriginal communities; or
- Government Aboriginal health funds are a source of funding.

5.4 Access to Foronial Gata or Lnformation

5.4.1 All human research projects that require access to coronial data or information must obtain endorsement from the *National Coronial Information System (NCIS) Research Committee* and ethics approval from the *Justice Human Research Ethics Committee* in addition to the approval of the Central HREC.

5.5 Access to WA Department of Justice data, facilities, staff, and/or clients

5.5.1 All human research projects that require access to WA Department of Justice data, facilities, staff, and/or clients must obtain endorsement from the Department of Justice's Research Application and Advisory Committee (RAAC) in addition to the approval of the WA Health Central HREC. Researchers should contact the RAAC team to discuss application requirements and whether the request is viable prior to making a submission.

6 Proportional ethics review

6.1 Determination of appropriate review pathway

All research project submissions are to be made through the RGS, regardless of the risk level posed by the proposed research.

6.1.1 The National Statement supports the idea that the risk level of the proposed research should guide the institution in determining the level of ethics review that is appropriate.

6.1.2 As part of the application the researcher is asked to designate the level of risk (in accordance with the guidance provided in Chapter 2.1 of the National Statement) of the research proposal. However, the final determination of the risk level of a project will be made by experienced CORE staff with input from committee members as required.

6.1.3 Applications for ethics review by the Central HREC will be assessed to determine the appropriate pathway for review by CORE staff trained and experienced in ethics and scientific review and the application of relevant guidelines and legislation.

6.1.4 CORE staff may draw on the expertise of the membership pool of the Central HREC to make the determination as required.

6.1.5 Where the CORE considers that a project may involve a departure from the ethics principles of integrity, respect for persons, beneficence and justice, the protocol must be considered at a full meeting and cannot be dealt with by the review pathways outlined in SOP 6.2.

6.1.6 Applications will be assessed to determine if they are eligible for:

- review by the lower risk review pathway.
- expedited ethics review.
- exemption from ethics review.

6.1.7 A report of the projects assessed by the review pathways described in SOP 6.

6.2 Lower risk review pathway

The National Statement defines lower risk research as “research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden.” Further, the National Statement defines minimal risk research as “research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience.”

6.2.1 A Lower Risk Review (LRR) Panel will be established to assess each application that is eligible for review via the Lower Risk Review Pathway. The LRR Panel will comprise:

- a CORE staff member who is trained and experienced in ethics and scientific review and the application of relevant guidelines and legislation, and
- two members of the Central HREC membership pool with appropriate expertise related to the proposal under review.

6.2.2 While the CPI can initially identify the proposed research as lower risk guided by the LRR toolkit, the CORE and, if required, the LRR Panel will make the final determination. Additional information will be requested from the CPI if required.

6.2.3 If the research involves access to participant records or data from a Commonwealth agency or private organisation (e.g., GP or private hospital) without the consent of the participant, Section 95, or Section 95A of the Privacy Act 1988 is applicable and therefore the project requires full ethics review.

6.2.4 If the appropriate consent is obtained to access the records or data of the participants from a Commonwealth agency or private organisation (e.g., GP or private hospital), Section 95, or Section 95A of the Privacy Act 1988 does not apply and therefore the project may be considered for review via the alternate review pathways described in SOP 6.2

6.2.5 External funding bodies may require that a project is reviewed by an HREC as a condition of funding regardless of the project's risk rating.

6.2.6 Multi-jurisdictional projects that may be eligible for review by the LRR Pathway should be discussed on a case-by-case basis with the CORE as there are variations in lower risk review processes across the country.

6.2.7 To facilitate their review, the LRR Panel members will require the following documents:

- All project documents requiring ethics review, (e.g., project protocol, information and consent forms, survey texts, advertising, and recruitment materials).
- Lower Risk Review checklist, and
- a summary of the review undertaken by the CORE.

6.2.8 LRR Panel members will review the submission and come to a decision within 7-10 calendar days of receipt of the application.

6.2.9 The LRR Panel will reach one of the following decisions by majority:

- Proposal is approved.
- Further information is required.
- Proposal is not suitable for review via the Lower Risk Review Pathway. It requires ethics review by the HREC and will be tabled at the next available and appropriate Central HREC meeting.
- Research is not approved.

6.2.10 The LRR Panel's decision and any requests for additional information will be collected by the CORE and communicated to the CPI via the RGS. Where relevant the appropriate section of the National Statement will be referenced in the communication.

6.2.11 Proposals approved by the LRR Panel must follow the same monitoring requirements as proposals that have been approved by a full committee review (SOP 7 Monitoring of Approved Projects).

6.2.12 In accordance with Section 2.3.9 of the National Statement "only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information". Consequently, any lower risk research proposal that will use personal information in medical research or personal health information and includes a request for a waiver of consent must be considered at a Central HREC meeting.

6.3 Expedited review

6.3.1 Expedited review of research proposals that have not been reviewed by the Central HREC previously, may be undertaken between scheduled meetings at the discretion of the Chair of the Central HREC.

6.3.2 A quorum must participate in the expedited review of the project but need not be physically present. The expedited review will be conducted in accordance with SOP 5 (Considerations in Ethics Review)

6.3.3 Research proposals with the potential for physical and/or psychological harm will not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and projects exploring sensitive personal, social, or cultural issues.

6.3.4 The Chair may undertake expedited review of:

- Amendments requesting:
  - a change of membership of the research staff, including changes to the CPI and/or PI role.
  - extensions of ethics approval
- progress reports.
- urgent amendments to previously approved protocols for safety reasons.
- other items of business such as adverse events.
- projects undertaken within the WA Health system to prevent or lessen a serious and imminent threat to the life, health, or safety of an individual or the public that requires the use or linkage of personal information from information systems held by the Department.

6.4 Exemption from ethics review

In accordance with the National Statement Section 5.1.15, some research may be eligible for exemption from ethics review. Where appropriate, exemption is granted, or not, by the institution responsible for the research.

6.4.1 Projects may be exempt from ethics review where they:

- involve only lower risk to participants and/or the community, and
- satisfies at least one of the conditions listed in National Statement Section 5.1.17 (a–d)

6.4.2 The process for seeking exemption from ethics review does not occur through RGS.

6.4.3 If a CPI believes their research proposal should be exempt from ethics review, they must approach the institution responsible for the research for a determination. The Central HREC or its delegate will provide advice to the institution if requested.

6.5 Non-research activities

6.5.1 Non-research activities should not be submitted via the RGS.

6.5.2 Projects that are a non-research activity are exempt from ethics review. A tool to help identify projects as research or not is available on the WA Health Central HREC website.

6.5.1.1 Quality assurance/ quality improvement activities

6.5.1.1 (i) Quality assurance/quality improvement activities should not be submitted for review via the RGS.

6.5.1.2 (ii) Quality assurance/quality improvement activities should be assessed through the relevant HSP's Governance Evidence Knowledge and Outcomes (GEKO) pathway, or equivalent, provided the relevant criteria are met.

6.5.1.2 Authorised prescriber

6.5.1.2(i) The Committee accepts applications from medical practitioners seeking to become Authorised Prescribers of an 'unapproved' therapeutic good with the Therapeutic Goods Administration (TGA).

6.5.1.2(ii) The medical practitioner's application for HREC approval to apply for Authorised Prescriber status with the TGA must be made in writing and provide sufficient evidence to justify the use of the 'unapproved' therapeutic good. More information on applying to be an Authorised Prescriber can be found on the TGA website or from the CORE or your relevant HSP research office

6.5.1.2(iii) Applications from medical practitioners seeking to become an Authorised Prescriber of an 'unapproved' therapeutic good should not be submitted via the RGS.

6.5.1.3 Case reports and case series

6.5.1.3(i) Case reports and case series should not be submitted via the RGS.

6.5.1.3(ii) Case reports, a report of a single individual with a unique disease or condition, or case series, a retrospective, noncomparative investigation that evaluates a group of patients with a known medical condition, disease, exposure, or who have undergone a similar procedure, are considered anecdotal and can proceed without ethics review.

6.5.1.3(iii) Case reports and case series must always withhold the identity of the participant(s).

6.5.1.3(iv) If publication is a possibility, researchers must discuss the publication with the participant (or their parent(s)/guardian if under the age of 18 years) and obtain their signed consent to publish.

6.5.1.3(v) Where consent cannot be obtained, guidance must be sought from the relevant HSP on a case-by-case basis. The matter may be referred to the Committee if deemed necessary.

7 Monitoring of approved projects

7.1 Monitoring

7.1.1 The Central HREC will monitor each approved project throughout its lifetime to ensure that it is conducted ethically, and in compliance with the approved protocol. In doing so the Central HREC and/or its representative may request from and discuss with the CPI any relevant aspects of the project.

7.1.2 The Central HREC may adopt any additional appropriate mechanism(s) for monitoring, as deemed necessary, including:

- random inspections of project sites, data, and signed consent forms.
- interview, with their prior consent, of project participants.

7.1.3 On-site monitoring or audits by sponsors, HSPs and the Central HREC may also be used to monitor specific projects and to randomly review the conduct of research in the WA Health system to inform planning, educational initiatives, and priorities and to ensure a high standard of research conduct is being maintained.

7.1.4 The Central HREC requires, as a condition of approval of each project, that the CPI immediately report anything that might warrant review of ethics approval of the protocol, including:

- proposed changes in the protocol.
- any unforeseen events that might affect continued ethical acceptability of the project.
- new information from other published or unpublished studies which may have an impact upon the continued ethical acceptability of the project, or which may indicate the need for amendments to the project protocol.

7.1.5 In determining the frequency and type of monitoring required for approved projects, the Central HREC will consider the degree of risk to participants in the project.

7.2 Annual progress reports

7.2.1 The Central HREC require an annual progress report for each approved proposal to be submitted *via* the RGS. The annual progress report is due, each year, on the anniversary of ethics approval of the proposal.

7.2.2 Continuing approval of the project will be subject to the submission of an annual progress report within three months of the due date. The review of any new amendments will be paused until a progress report is submitted.

7.2.3 Repeated failure to submit annual progress reports will result in the project being tabled at the next available and appropriate Central HREC meeting where suspension and/or withdrawal of ethics approval for the project will be considered.

7.2.4 The following information must be provided in the annual progress report:

- progress to date, including details of publications, and difficulties encountered.
- site specific participant recruitment.
- maintenance and security of records and information.
- compliance with the approved protocol.

- compliance with any conditions of approval.
- changes to the protocol or conduct of the project.
- changes to the personnel or contact details of the CPI.
- adverse events and any changes to the research arising from these events.
- complaints relating to the project.

7.2.5 Annual progress reports shall be, in the first instance, reviewed by the CORE and may be referred to the Chair or next relevant Central HREC meeting.

7.3 Site and project final reports

7.3.1 Site final and project final reports should only be submitted once all research activity has been finalised at the relevant site that is participating in the research.

7.3.2 If applicable, the plan for the ongoing care of participants should be reported.

7.3.3 Project final reports will be reviewed by a full Central HREC meeting.

7.3.4 Once the researcher receives the project final report approval letter, no further research activity can occur.

7.3.5 Research findings generated from the research should be disseminated to participants as per Section 3 Element 6 of the *National Statement*.

8 Suspension and/or Withdrawal of Ethics Approval

8.1 Suspension and/or Withdrawal of Ethics Approval

8.1.1 The Central HREC has the right to suspend and/or withdraw ethics approval.

8.1.2 The Central HREC will consider suspending or withdrawing ethics approval if:

- the continuation of the research represents an unacceptable risk or disadvantage to participants.
- there has been significant deviation from the protocol.
- satisfactory annual progress reports have not been received by the Central HREC by the due date.
- the annual progress report is overdue and a request for an extension to the due date has not been received within three months of the original due date of the annual progress report.

8.1.3 If the ethics approval for a project is suspended, the CPI will be notified that no further activity can be conducted until the matter is resolved.

8.1.4 Ethics approval will remain suspended until researchers have addressed the Central HREC's concerns to their satisfaction.

8.1.5 If the project's approval is suspended or withdrawn, project activity must cease immediately and cannot be recommenced without the written approval of the Central HREC.

8.1.6 When the ethics approval for a research project is withdrawn the researcher must:

- halt the research immediately.
- inform the participants of the withdrawal where possible.
- inform the institution/s where the project is being conducted of the withdrawal.
- plan to meet the needs of participants.
- notify the Central HREC and any institutions where the research was being conducted that these steps have been taken.

8.1.7 Where a project also holds ethics approval from another institution or review body, the CPI must notify the institution(s) or review bodies that they have had their ethics approval suspended/terminated.

8.2 Notification of suspension and/or withdrawal of ethics approval

8.2.1 If the ethics approval for a project is suspended or withdrawn a letter to that effect will be sent to:

- the CPI and the PI(s).
- the contact person nominated for the project (typically the CPI delegate or PI delegate).
- and the Executive of the HSP(s) Head of Department / School / Research Organisation overseeing the project.

8.2.2 The letter of notification will include:

- the name of the project and its project reference number (PRN).

- the date of ethics approval and the date the approval was suspended or withdrawn.
- a description of the concern/s of the Central HREC.
- notice that the concerns raised by the Central HREC must be addressed within 28 days of receipt of the letter.
- the response should include a description of the implications for participants and how risks will be mitigated to prevent adverse outcomes.
- a statement that, in line with the requirements of Section 5.4.17 of the *National Statement*, that suspend ethics approval will be either withdrawn or suspended until the matter is resolved to the satisfaction of the Central HREC.

8.2.3 If the matter remains unresolved 28 calendar days from date of the notification of suspension of ethics approval, a second letter will be sent from the Chair. This letter will advise that the project's ethics approval has been withdrawn.

8.3 Urgent suspension of Ethics Approval

8.3.1 If the Central HREC or the Chair, acting on behalf of the Central HREC, considers the urgent suspension of a research project is necessary, this notification will come from the CORE in the form of a telephone call or email.

8.3.2 The suspension of ethics approval will be confirmed in writing within 24 hours *via* RGS.

8.4 Reinstatement of Ethics Approval

8.4.1 While the project is suspended, the Central HREC and relevant HSP(s) will take reasonable steps to determine whether the project should continue.

8.4.2 The process of determining whether the project should continue will be conducted fairly and with respect to the investigators, the participants and others involved in the project.

8.4.3 Two designated members of the Central HREC, a member of the CORE trained and experienced in ethics and scientific review and the application of relevant guidelines and legislation will in association with RGOs from relevant HSP(s) undertake this assessment.

8.4.4 A recommendation of whether the project can continue or not will be made to the Executive of the relevant HSP(s).

8.4.5 If the case for recommencement of the research is not accepted by the relevant HSP(s) Executive, the site authorisation for the project at that site will be withdraw n.

8.5 Reinstatement of Ethics Approval (WA Department of Health Only)

8.5.1 Where a project that is being conducted at the Department, or using departmental resources, is not being or cannot be conducted in accordance with the approved study protocol, or where remedial measures are insufficient to address the concerns raised by the Central HREC this must be reported to the Chair and Director, OMRI.

8.5.2 The Chair and Director, OMRI may then determine whether the project's ethics and governance approvals will be terminated.

8.5.3 The CPI, PI, the contact person nominated for the project (typically the CPI delegate or PI delegate), and the Head of Department/School/Research Organisation overseeing the project will be informed of the decision in writing by the Chair *via* the Director, OMRI.

8.5.4 This letter will advise whether the project's ethics and governance approval has been terminated or if the suspension of approval has been removed.

9 Adverse Event and Safety Reporting

9.1 Adverse Events

9.1.1 An adverse event is defined in the International Council for Harmonisation's Guidelines for Good Clinical Practice (ICH GCP) and refers to: "*Any untoward medical occurrence in a patient or clinical investigation subject administered an investigational product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product, whether related to the investigational product.*"

9.1.2 CPIs of interventional studies must have a Data Safety Monitoring Board (DSMB) or equivalent in place to monitor the safety of the participants as per Section 5.4.5 of the NHMRC's *National Statement*.

9.1.3 Data Safety and Management Boards should be set up in accordance with the NHMRC's guidance document *Data Safety Monitoring Board (DSMB) 2018.*

9.2 Adverse Event Reporting

9.2.1 The Central HREC has adopted the adverse event reporting requirements detailed in *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)* published by the NHMRC.

9.2.2 Investigators must also comply with all mandatory reporting obligations required at the site(s) where the project is being conducted at (refer to the *WA Health Research Governance Framework).*

9.2.3 All safety reports must be submitted *via* the RGS.

9.3 Safety Reports

9.3.1 Events requiring the submission of a safety report to the Central HREC, (as described in the NHMRC's Safety monitoring, and reporting in clinical trials involving therapeutic goods, 2016) include:

- Serious breaches of protocol.
- Significant Safety Issues (SSI).as required.
- Sudden Unexpected Serious Adverse Reactions (SUSAR).
- Unexpected Serious Adverse Device Effect (USADE).

9.3.2 These types of events are defined in the NHMRC's *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016),* and the reporting requirements are described therein.

9.3.3 It is essential that all clinical trial investigators and their delegates understand the safety reporting requirements expected of them.

9.3.4 Any urgent reports as described in the NHMRC's *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)* will be forwarded to the Chair for out of session review.

9.3.5 The Chair may request input from one or more Central HREC members with expertise relevant to the reports content.

9.3.6 Safety reports reviewed out of session will be tabled at the next available and appropriate Central HREC meeting for review or noting.

9.3.7 Review of safety reports will result in one or more of the following actions:

- acknowledgement of receipt of the report.
- the event will be noted.
- additional information will be requested.
- ethics approval will be suspended with immediate effect.
- ethics approval will be withdrawn with immediate effect.
- other actions as recommended by the Committee.

9.3.8 Where immediate action is required, the CORE will contact the CPI/PI and their delegates in the form of a telephone call or email as soon as possible to inform them of the required actions.

9.3.9 The CPI will be notified by letter *via* the RGS of the outcome of review.

9.3.10 Notification and outcomes of the Central HREC's decisions and/or requests will be recorded in RGS.

9.4 Urgent Safety Measures

9.4.1 Responding to an adverse event may require an Urgent Safety Measure (USM) to eliminate an immediate hazard to participant welfare.

9.4.2 While a USM may be implemented prior to Central HREC review of the safety report, they should be notified in writing that the measure has been taken as soon as practicable.

9.5 Annual Safety Reports

9.5.1 Interventional research projects are required to submit annual safety reports to the Central HREC, regardless of whether any qualifying safety events have occurred.

9.5.2 Annual safety reports must include the following information:

- details of any planned actions resulting from safety reports.
- current approved product information (e.g., Investigator's brochure), if appropriate.
- executive summary from the DSMB or equivalent, if appropriate.
- any other reports consistent with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH-GCP).

9.5.3 Investigator's brochure updates, aggregate safety reports and DSMB meeting minutes provided to sites during an annual reporting period which state that the risk/benefit analysis for the investigational product is unchanged **and** that no amendments to the trial

protocol are required should be summarised in the annual safety report instead of being reported *ad hoc*.

9.5.4 Annual safety reports will be reviewed under the same process described above for safety reports.

10 Amendments

10.1 Amendments to Project Documentation

10.1.1 Proposed changes to approved research projects (including requests for extensions to the duration of ethics approval) must be submitted as an amendment *via* the RGS.

10.1.2 The amendment request must describe the nature of the proposed change(s) to the project and the reasons for making the change(s).

10.1.3 An assessment of any ethical implications arising from the change(s) to the conduct of the project should also be provided.

10.1.4 All documents that are being updated must be provided in both tracked changes (with changes in red line) and clean copies with updated version control.

10.1.5 Documents that have not been reviewed by the Central HREC previously should be submitted in clean copy only.

10.1.6 If there are substantial changes required to project documentation, a summary of changes may be requested by the CORE.

10.2 Urgent Amendments in Response to Safety Issues

10.2.1 Urgent protocol amendments required to address safety reasons can be implemented immediately, prior to ethics approval, provided an imminent risk to participant safety is demonstrated.

10.3 Extensions of Ethics Approval

10.3.1 Extension of ethics approval is limited to a maximum period of three years.

10.3.2 Any further extension beyond 3 years will be granted at the discretion of the Chair who may request that the research proposal is resubmitted as a new application.

10.3.3 Projects that have ceased all contact with participants do not require an extension of ethics approval if only de-identified data is being used for analysis and there are no ethical issues associated with the analysis or subsequent publication of the project.

This provision **does not** apply to research projects accessing data sets held by the Department; such projects require ongoing ethics approval until all publications have been completed.

10.4 Delegated Review of Amendments

10.4.1 Ethics review of amendments may be undertaken by the Chair or delegated to members of the Central HREC or to the CORE at the discretion of the Chair of the Central HREC.

10.4.2 The following changes to an approved project can be delegated to one or more members of the Central HREC's membership pool or to the CORE and are eligible for review outside the Central HREC's meeting schedule:

- minor amendments (including changes to the investigators conducting the project).
- requests for extension of ethics approval.
- urgent amendments to approved protocols for safety reasons.

10.4.3 The delegated reviewers can, at their discretion, request an amendment be reviewed by the Central HREC at the next available and appropriate meeting, provided the request and necessary documentation has been received by the CORE.

10.4.4 Reviewers may consult with data custodians regarding amendment requests where appropriate."

10.5 Notification of the Outcome of the Review of Amendments

10.5.1 The CPI will be advised of the outcome of the review within five working days of the completion of the review. A letter will be issued *via* the RGS.

10.5.2 If further information, clarification, or modification is required, a letter that explains why clarification or modification is required will be issued *via* the RGS. The letter will also set out the information that needs to be provided. Where possible, requests for additional information, clarification or modification should refer to the *National Statement* or relevant legislation.

11 Suspension of a Research Project by the Coordinating Principal Investigator

11.1 Suspension of a Research Project by the Coordinating Principal Investigator

11.1.1 If an approved project has not been started or has been terminated earlier than anticipated the Committee requires that:

- The PI(s) inform the Central HREC and the relevant RGO *via* a Site Final Report in the RGS.
- The CPI informs the Central HREC of their decision to discontinue a research project *via* a Project Final Report submitted in the RGS.

11.1.2 If the CPI suspends an approved project, then the CPI must submit an Amendment *via* the RGS explaining:

- why the project has been suspended.
- the measures taken to inform consented participants as soon as possible.
- the measures being taken to ensure the participants safety and ongoing care.

11.1.3 Prior to research activities resuming, the CPI must demonstrate that the issues that led to the project's suspension have been adequately addressed, and that the Sponsor has granted permission to recommence.

11.1.4 The project may recommence only after receipt of a written notification from the Central HREC and RGO to that effect.

11.1.5 If the research project is not resumed, the CORE will request a site final report and information (if not previously provided) about the actions being taken to ensure the safety and ongoing care of participants.

11.1.6 The submission of the site final report can only occur after the plan for the ongoing management of participants is approved by the Central HREC and relevant institutions.

11.1.7 After approval of the site final report, the investigators must enact and comply with the approved Retention and Disposal Plan.

12 Complaints Regarding the Review of an Application

12.1 Complaints about the ethics review of an application

12.1.1 All complaints must be submitted in writing by the CPI and be addressed for the attention of the Chair of the Central HREC. Also, the CPI is required to lodge a complaint form in RGS.

12.1.2 Any complaints or concerns about the Central HREC's review processes should be sent by email to *HREC@health.wa.gov.au.*

12.1.3 The CORE will send an acknowledgment to the CPI within seven calendar days of receipt of the complaint. The CORE will notify the Chair and the Director, OMRI.

12.1.4 The Chair of the Central HREC or their delegate, provided that they did not attend the Central HREC meeting which is the subject of the complaint, will investigate the complaint and its validity, ascertaining whether the Central HREC acted in accordance with its ToR, SOPs, the *National Statement* and otherwise acted in a fair and unbiased manner at the relevant meeting. Following this assessment, the investigator who examined the complaint will make a recommendation to the Chair of the meeting that first reviewed the project on the appropriate course of action.

12.1.5 The investigation will be conducted within 30 calendar days from the date the complaint was lodged, exceptional circumstances not-withstanding.

12.1.6 The complainant will be informed of the outcome of the investigation within 7 calendar days of the investigation being completed.

12.1.7 If the complainant is not satisfied with the outcome of the investigation, they can request that the Chair of the Central HREC refer the complaint to the DG, or their delegate.

12.1.8 The Chair of the Central HREC will provide the DG or delegate with all relevant information about the complaint, including:

- details of the complaint.
- material reviewed in the investigation.
- the outcome of the investigation.
- the recommended course of action.
- any other relevant documentation.

12.1.9 The DG or delegate will determine whether further investigation is warranted. Where no further investigation is required, the DG or delegate will inform the complainant and the Chair of Central HREC.

12.1.10 If there is to be further investigation, then the DG or delegate will establish a panel to consider the complaint. The Panel will include, at least, the following members:

- the DG or the DG's nominee as the convenor of the Panel.
- a person from the Central HREC membership pool who was not involved in the meeting that was subject of the complaint.
- a person experienced in the ethics review of projects (who is not a member of the meeting that was the subject of the complaint).
- an expert in the discipline of the project under consideration, and
- additional members, as required by the DG.

12.1.11 The Panel may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

12.1.12 The panel will assess the complaint and its validity, ascertaining whether the Central HREC acted in accordance with its ToR, SOPs, the *National Statement* and otherwise acted in a fair and unbiased manner.

12.1.13 The DG or delegate will notify the complainant and the Central HREC of the outcome of the investigation in writing.

12.1.14 The outcomes may include:

- dismissing the complaint, or
- referring the complaint back to the Central HREC for reconsideration in the light of findings of the panel.

12.1.15 The panel may also make recommendations about the operation of the Central HREC including:

- review of the ToR.
- review of SOPs.
- review of the Central HREC membership.

12.1.16 The panel or the DG or delegate cannot provide ethics approval.

12.1.17 If the Central HREC is requested to review its decision, then the outcome of this review by the Central HREC will be final.

12.1.18 If the complainant is not satisfied with the decision of the DG, then depending on the nature of the complaint the matter may be referred for external review to the Ombudsman of Western Australia, the Health, and Disability Services Complaints Office or the State or Federal Information Commissioner.

12.1.19 The details of the review must be recorded in the RGS, including the date of review, who conducted the review, the outcome of the review and any additional information that is required.

13 Complaints and Breaches – Research Integrity

13.1 Complaints and Breaches

The Australian Code for the Responsible Conduct of Research, 2018, (The Code) states: "*Institutions have an obligation to encourage and support responsible research conduct. They are accountable to funding organisations and the Australian community for how research is conducted*."

13.1.1 A breach is defined as a failure to meet the principles and responsibilities of The Code and may refer to a single breach or multiple breaches. Investigating research integrity issues is the responsibility of the Institution. Examples of breaches of The Code include, but are not limited to, the following:

- Not meeting required research standards (e.g., conducting research without approval, misuse of research funds).
- Fabrication, falsification, misrepresentation (e.g., fabrication or falsification of research data or source material).
- Plagiarism (e.g., plagiarising someone else's work).
- Research data management (e.g., failure to appropriately maintain research records).

13.1.2 A potential breach of the Code occurs when a concern is raised or identified that one or more researchers have conducted research that is not in accordance with the principles and responsibilities of The Code.

13.1.3 Complaints regarding the conduct of Committee approved projects can be made by participants, researchers, staff of institutions, or any other interested parties.

13.1.4 Where it is possible a complaint has breached the standards governing the conduct of research, it will be handled in accordance with The Code and the relevant research integrity policy of the Institution where the research is being conducted.

13.2 Reporting a Complaint or Breach

13.2.1 Researchers are required, as a condition of approval, to report any complaints received or potential breaches identified to the CORE immediately via HREC@health.wa.gov.au

13.2.2 Reports of complaints or potential breaches received by the CORE will be referred, as a matter of urgency, to the HSP(s) where the project is being conducted for investigation in accordance with that HSP's research integrity policy. If the project concerned involves accessing WA Health datasets or Data Linkage the matter will be managed in accordance with the Department's Research Integrity Policy

13.2.3 Complaints and notifications of potential breaches can be made in a variety of ways, *via* phone contact, written correspondence, or in person. Depending on the method of contact, consent to share details to allow the complaint to be dealt with may be required.

13.2.3 A report of a potential breach in the conduct of a Central HREC approved project should include the following information:

- the nature of the breach.

- the steps taken to prevent any further injury, damage, or disclosure of confidential information.
- whether any breach was inadvertent, negligent, or intentional,
- proposed changes to the protocol because of the breach, and
- the sensitivity of any information concerned, including the amount and type of information and the level of identifiability.

13.2.4 Complainants have the right for their complaint to be:

- received and treated in confidence.
- treated with respect and dignity.
- addressed in a spirit of helpful co-operation.
- dealt with in a manner that includes appropriate communication and progress updates.
- treated as genuine and thoroughly investigated.

13.2.5 The CORE will notify the relevant personnel at the site of the complaint as soon as possible after notification of the complaint.

13.2.6 The CORE will send an acknowledgment to the complainant and notify the CPI and relevant PI(s), of the complaint, advising that the complaint will be investigated by the institution where the research is being conducted in accordance with its research integrity policy.

13.3 Investigating a Complaint or Breach

13.3.1 Where it is possible a complaint has breached the standards governing the conduct of research, it will be handled in accordance with the Code.

13.3.2 The relevant personnel at the HSP where the project is being conducted will investigate the complaint and its validity and provide a report and recommendation to the Central HREC within 30 days of receipt of the complaint.

13.4.3 The outcome of the institutional review must be notified to the CORE, recorded in the RGS and within the project's file. The entry in the RGS must include the date of review and by whom it was conducted and any additional relevant information.

13.3.4 The CPI and relevant PI(s) will be notified of any changes to the ethics approval for the project concerned by the Chair within 5 days of receipt of the review report and recommendations.

14 Multicentre Research - Ethics Review Pathways

14.1 Ethics Review in WA

14.1.1 All WA Health sites accept the ethics and scientific review undertaken by the Central HREC.

14.1.2 The requirements for additional ethics approval from the *WA Aboriginal Health Ethics Committee* (WAAHEC) and *National Coronial Information System (NCIS) Research Committee* are outlined in SOP 5.3 (*WA Aboriginal Health Ethics Committee*) and 5.4 (*Access to Coronial Data or Information) respectively*.

14.1.4 Research being conducted at non-WA Health sites may require separate ethics review at that institution, unless the institution has a pre-existing agreement with WA Health.

14.2 Inter-Jurisdictional Ethics Review - National Mutual Acceptance (NMA)

14.2.1 The National Mutual Acceptance (NMA) scheme has been implemented in public health organisations across all Australian states and territories.

14.2.2 Multi-centre research projects being conducted at public health organisations in Australia must be ethically and scientifically reviewed only once by an NHMRC Certified Lead HREC participating in the NMA scheme.

14.2.3 All WA Health sites accept the ethics and scientific review undertaken by an NHMRC Certified Lead HREC participating in the NMA scheme. Conditional to this acceptance is the submission of original copies of all documents to each relevant RGO *via* RGS

14.2.4 Some projects may require additional specialist review.

14.2.5 In WA, projects that meet the criteria set out in Section 5.3 (*WA Aboriginal Health Ethics Committee*) require the specialist review of the WAAHEC.

14.2.6 Projects that meet the criteria set out in Section 5.4 (*Access to Coronial Data or Information*) require the specialist review of the NCIS Research Committee and Justice Human Research Ethics Committee.

14.2.7 For research involving sites across multiple Australian jurisdictions and including at least one WA health system site, NMA must be used to ensure efficient review.

15 Application Requirements

15.1 Application Requirements

15.1.1 All applications for ethics review, be it for single site or multi-centre research, must be submitted *via* the RGS.

15.1.2 Applications can be submitted at any time and will be assigned for review at the next appropriate meeting.

15.1.3 Applications must be submitted in the appropriate format, be complete, and include all documentation as determined by the Central HREC.

15.1.4 Researchers must provide a data management plan as part of their application to the Central HREC if the researcher is requesting data held or linked by the Department.

15.1.5 Projects applying for a waiver of consent should ensure they address all the criteria set out in Section 2.3.10(a)-(i) of the *National Statement* in their RGS application.

15.1.6 Projects applying for a waiver of consent for access to participant records or data from a Commonwealth agency or private organisation (e.g., GP or private hospital) should also ensure that they address the criteria set out in the approved guidelines under Section 95 or 95A of the Privacy Act 1998 (where applicable).

15.1.7 Projects that involve the recruitment of incapacitated adults under the provisions of the GAA should ensure that all necessary information on how the GAA will be implemented is included in their submission.

15.1.8 The CPI or delegate is responsible for submitting the ethics application.

15.1.9 The CPI or delegate is also responsible for inviting project team members to the project on RGS.

15.1.10 Non-WA Health employees seeking access to the RGS are required to provide a referee who is employed by WA Health.

15.2 Fees for Review of Applications

15.2.1 A fee will not be charged for non-commercial applications submitted for assessment by the Committee.

15.2.2 Fees must be charged in full for all commercially sponsored research projects, except for teletrials where the Department may choose to cover all or part of the costs in-kind to encourage participation during the set -up of a teletrial.

15.2.3 Where commercial sponsor charges apply, the payment must be invoiced directly to the sponsor to cover the review costs incurred by the site, irrespective of whether the research project commences.

15.2.4 Protocol amendments that introduce significant changes or which introduce major new safety considerations, and which require full Central HREC review may attract a higher fee for those commercially sponsored projects. This includes the addition of new sub-studies.

15.2.5 Fees for reviewing commercial applications will apply and are outlined on the WA Health Central HREC website and in Section 9 of the *Research Governance Procedures.*

15.3 Application Forms Required for an Intra-jurisdictional (within WA) Application

15.3.1 For single-centre or multi-centre research that will involve one or more WA Health sites and will only be conducted within WA, the WA Health Ethics Application Form (WAHEAF) should be submitted to the Central HREC for review *via* RGS.

15.4 Application Forms Required for an NMA Application

15.4.1 For multicentre projects conducted at WA Health sites, submission of the Human Research Ethics Application (HREA) form and the Western Australian Specific Module (WASM) is required irrespective of whether the Lead HREC is within or outside of WA.

15.4.2 The WASM is a WA-specific addendum to the HREA that enables the reviewing committee to understand and apply the WA legislative requirements that affect research conducted in WA. Guidance on additional forms that should be submitted to meet other jurisdictional requirements is available from the *NMA Standard Principles for Operation.*

15.5 Validation of Applications for Review

15.5.1 Applications will be checked for completeness and validity by the CORE prior to their acceptance for review by the Central HREC.

15.5.2 Researchers will be advised if their application is incomplete and/or incorrect during the RGS validation process. Additional information will be requested if it is required.

15.5.3 The CORE will acknowledge acceptance of the application for ethics review by marking each relevant document as valid in RGS.

15.5.4 When the application is complete it will be added to the agenda for the next appropriate meeting.

15.5.5 Central HREC members will be advised that the application and associated documents are available for review in the RGS at least seven calendar days prior to the meeting at which the submission will be discussed.

16 Record Keeping

16.1 Record Keeping

16.1.1 The RGS is a web-based Information Technology (IT) platform, that facilitates the preparation, submission, review, approval, and monitoring of human research projects conducted at WA Health Sites.

16.1.2 The Central HREC's activities, including agendas and minutes for all meetings, are maintained in an electronic format within the RGS.

16.1.3 All project records received and reviewed will be maintained electronically in the RGS in accordance with Section 5.2.15-20 of the *National Statement.*

16.1.4 Within the RGS, each project record will be kept confidential and in accordance with the *State Records Act 2000* and any other applicable legislation.

16.1.5 The RGS project record will include:

- a unique project identification number.
- the title of the project.
- the names of the Coordinating Principal Investigator (CPI), the Principal Investigator(s) (PI(s)) and other project team members.
- the name of the institution or organisation responsible for the project; the Sponsor.
- the decisions of the HREC and the dates those decision were made.
- the terms and conditions, if any, of approval of the project.
- whether approval was by expedited review.
- action taken to monitor the conduct of the project.
- a copy of the application, including signatures, all approved documents, material used to inform potential participants and any relevant correspondence (including that between the applicant and the CORE).
- the relevant records of the Committee, including minutes and related correspondence.

16.1.6 To ensure confidentiality, all paper documents provided to or produced by members, which are no longer required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the CORE for disposal.

16.1.7 Records pertaining to projects will be held for sufficient time to allow for future reference. Retention periods will comply with the *General Retention and Disposal Authority for State Government Information* issued by the State Records Office and the Department's *Information Retention and Disposal Policy.*

17 Reporting Requirements

17.1 Meeting Minutes

17.1.1 The minutes of each meeting will be available to the DG following ratification by the Central HREC.

17.2 Annual Progress Report

17.2.1 The Central HREC will provide the DG with a progress report each calendar year.

17.2.2 The report will contain updates on:

- membership and changes to membership.
- number of meetings held.
- number of applications reviewed, approved, and rejected.
- any issues encountered by the Central HREC while monitoring research activity.
- a description of any complaints received and the outcome.
- a description of any projects where ethics approval has been suspended or withdrawn and the reason(s) for suspension or withdrawal of approval.
- general issues of note.

17.3 Australian Health Ethics Committee (AHEC)

17.3.1 The Central HREC will provide reports to the *Australian Health Ethics Committee* in accordance with the requirements of the NHMRC and will comply with all statutory reporting requirements.

17.4 Quarterly Reports

17.4.1 The Central HREC will provide a report on the projects it has approved for each quarter of the year. These reports will include the project summary provided by researchers in their application form. Researchers will be asked to provide their consent before the project summary can be included in the quarterly report.

17.5 Public Facing Reports

17.5.1 The Central HREC's ToR, SOPs Annual Reports, Quarterly Reports, and compliance with *National Statement* membership requirements will be posted on the WA Health Central HREC website and will be made available upon request.

18 Communication

18.1 Communication between the Central HREC and Researchers

18.1.1 The Central HREC will have a public facing webpage which will include contact information, these SOPs, the Central HREC's ToR, guidance documents and reference materials on research application processes and research conduct (including but not limited to, the National Statement and The Code). Furthermore, the home page of the RGS will provide researchers with access to the same information.

18.1.2 The Central HREC and CORE will engage in open communication with researchers via telephone, emails, and face to face meetings as appropriate.

18.1.3 The CORE, on behalf of the Central HREC, will provide researchers with education and guidance on ethics review and the preparation of ethics submissions. Further, where possible, the CORE will provide researchers with relevant documentation and training opportunities to address specific issues relating to the ethics review of their project.

18.1.4 The CORE, on behalf of the Central HREC will notify researchers of the HREC's decision via the RGS within 3 working days of the decision being finalised.

18.1.5 Where modifications to the application are requested, communication will be managed within the RGS. In some instances, the request may be provided in an email or communicated informally over the telephone. Such telephone conversations will be followed by an email detailing the conversation and instructing the researcher on how to respond to the request.

18.1.6 Communication between the CORE and a research sponsor should be limited and regulated to avoid undue influence on the review process.

19 Research Governance and Data Governance

19.1 Research Governance

19.1.1 The Committee will be responsible for ethics review and oversight only. Matters of research governance are the responsibility of the relevant institution(s). The contact details of the WA Health RGOs can be found on the *RGS*.

19.2 Data Governance

19.2.1 Where the applicant is requesting data held or linked by the Department, the DG or their delegate is responsible for granting approval for the use or disclosure of the data in accordance with relevant departmental policies.

19.2.2 Researchers are required to contact ISPD Client Services when requesting access to data held or linked by the Department to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data held or linked by the Department can be found on the *WA Data Linkage Services* website.

19.2.3 Where access to data held by PeopleWA is being sought, researchers are required to contact the PeopleWA team in the Office of Digital Government, Department of Premier and Cabinet to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data held or linked by PeopleWA can be found on the *PeopleWA* website.

19.2.4 Where data linkage *via* the Population Health Research Network (PHRN) is being sought, researchers should contact the PHRN team at the University of Western Australia to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data linked by the PHRN can be found on the *PHRN* website.

19.2.5 Where the applicant is requesting access to data collected at WA Health sites under the *Health Services Act 2016*, a Data Request Form should be completed for review and approval by the relevant data custodian/s as part of the Site Authorisation process.

19.2.6 All researchers conducting research within WA Health must comply with the Department's Information Security Policy (MP 0067/17) and Cloud Policy (MP 0140/20). This includes ensuring that electronic devices are assessed as appropriate for use by the institution of the site/s involved. Breaches to data security should be reported to the Committee and the relevant RGO of the site/s where the project is conducted as soon as practicable.

19.2.7 Researchers will be requested to provide a data management plan for projects involving access to health data as part of their application to the Central HREC.

20 Review of Standard Operating Procedures and Terms of Reference

20.1 Review of Standard Operating Procedures and Terms of Reference

20.1.1 The SOPs and ToR will be reviewed at least every three years and amended, as necessary.

20.1.2 Minor amendments to the SOP and ToR can be actioned by the CORE.

20.1.3 A minor amendment means a correction or change which is administrative in nature and does not significantly change the specific meaning, purpose, or intent of the document.

20.1.4 For major amendments, including changes in meaning, purpose, or intent, that are proposed by a Central HREC member:

- The proposal must be in writing and circulated to the members of the Central HREC for consideration.
- The Chair of the Central HREC may also seek the views of Central HREC members to help inform their decision.
- The views of the Chair of the Central HREC and any members should be discussed at the next scheduled meeting of the Chair of the Central HREC and their delegates, and a vote taken at that meeting.
- Any delegate unable to attend the meeting may provide their views in writing.
- The proposal shall be ratified if two thirds of the delegates of the Chair of the Central HREC agree to the amendment.
- The CORE shall send the amendment to the DG on behalf of the Chair of the HREC for consideration and approval where appropriate.

20.1.5 For amendments proposed by the DG or their delegate:

- the DG or their delegate will send the proposal to the Central HREC and seek the views of any relevant person.
- The DG or their delegate will consider the views of the members of the Central HREC and other relevant persons and will determine whether the amendment should be made.

This document can be made available in alternative formats on request for a person with a disability.